

**EPA REGISTRATION NUMBER 59639-183 – VOL. 2**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

JAN 16 2013

Sue Shen  
Regulatory Project Manager  
Valent U.S.A. Corp.  
2301 Ohio Drive, Suite 137  
Plano, TX 75093

Subject: Submission of 1 Year Storage Stability and Corrosive Characteristic Report  
Nipsit Suite Cereals of Seed Protectant  
EPA Registration No. 59639-183

Dear Ms. Shen:

The conditional data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A copy of the review is enclosed. Should you have any questions, please contact me at 703 308-8043 or [lewis.marianne@epa.gov](mailto:lewis.marianne@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Marianne Lewis", written over a vertical line.

Marianne Lewis  
Biologist  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JAN 14 2013

**MEMORANDUM:**

Subject: Storage Stability and Corrosion Characteristics  
EPA Registration Number: 59639-183  
Product Name: NipsIt™ SUITE Cereals OF Seed Protectant  
DP Barcode: 407913  
Decision Number: 473392  
PC Code: 044309, 113501, 125619

From: Julie Chao, Team Reviewer  
Venus Eagle, Product Manager 1  
Insecticide-Rodenticide Branch  
Registration Division

*Julie Chao 1/14/13*  
*Venus Eagle 1/14/13*

To: Marianne Lewis, Team Reviewer  
Insecticide-Rodenticide Branch  
Registration Division

Applicant: Valent U.S.A. Corporation  
1600 Riviera Avenue, Suite 200  
P.O. Box 8025  
Walnut Creek, CA 94596-8025

**FORMULATION FROM SUBJECT PRODUCT LABEL:**

	% by weight
<u>Active Ingredients:</u>	
Clothianidin .....	2.93%
Metalaxyl .....	0.88%
Metconazole .....	0.44%
<u>Other Ingredients:</u> .....	95.75%
Total:	100.00%

## **BACKGROUND:**

The registrant has submitted a study (MRID 49008401) which contains the results from a one year test of storage stability and corrosion characteristics (Guidelines 830.66317 and 830.6320). The study was conducted in compliance with Good Laboratory Practices (40 CFR §160).

## **SUMMARY OF FINDINGS:**

The test material used in the study was the subject product. To evaluate stability, the test material was stored periods of three, six, nine, and twelve months under ambient warehouse temperature conditions (12.16 to 28.30 °C), in representative commercial packaging (white HDPE bottles with polypropylene caps with induction seals). Two samples were evaluated each sampling interval. The concentration of active ingredient was measured using high performance liquid chromatography (Analytical Method VAM-22k-001). The results, summarized in the table below, are within the established certified limits.

**Table 1: % Clothianidin, Metalaxyl, and Metconazole at 3-Month Intervals**

<b>Sampling Interval</b>	<b>% wt/wt Clothianidin*</b>	<b>% wt/wt Metalaxyl</b>	<b>% wt/wt Metconazole</b>
Initial	3.16	0.940	0.460
3 months	3.03	0.903	0.445
6 months	3.08	0.910	0.448
9 months	2.97	0.902	0.443
12 months	3.02	0.895	0.438

\* Mean concentration

To evaluate corrosion, visual evaluations of the test container and test material were performed at each sampling interval. Sample weights were also recorded at each 3-month interval. There were no observed physical changes in the appearance of the test container over the duration of the study period. At the 3, 6, 9, and 12 month intervals, the test substance showed a small amount of top clearing (i.e., separation), although shaking returned the material to a uniform suspension. There were no significant changes in weight over the duration of the study.

## **CONCLUSION AND RECOMMENDATIONS:**

The results support the conclusion that the product is stable for at least one year in ambient storage conditions, and that the product is not corrosive to commercial packaging. This submission satisfies Guidelines 830.66317 and 830.6320, and MRID 49008401 has been classified as "Acceptable."

Due to the tendency for the material to separate, it is appropriate for the label to include instructions about how to ensure a uniform suspension prior to use (e.g., "Shake before use"). It is noted that the label already contains the statement, "Always mix product thoroughly before use."



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

December 12, 2012

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

VALENT U.S.A. CORPORATION  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 03-DEC-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 927545

Resubmission: ☒ Yes ☐ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☐ Yes ☒ No

Company: 59639 VALENT U.S.A. CORPORATION

V

Risk Manager: Registration Division, Risk Management Team 1

Product #: 59639-183 Product Name: NIPSIT SUITE CEREALS OF SEED PROTECTANT

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 26-Nov-2012

id

OPP Rec'd Date: 03-Dec-2012

id

Front End Date: 03-Dec-2012

id

Risk Manager Send Date: 03-Dec-2012

id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

storage stability & corrosion characteristics study

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 59639-183	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NipsIt SUITE Cereals OF Seed Protectant	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Valent USA Corp. 1600 Riviera Drive, Suite 200, Walnut Creek, CA 94596  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Submit SS-CC study report per EPA's request on 12-21-2011

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 45 gal, 260 gal		5. Location of Label Directions <input checked="" type="checkbox"/> On Labeling	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Sue-Chi Shen		Title Project Manager	
		Telephone No. (Include Area Code) 214-784-5536	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Project Manager	
4. Typed Name Sue-Chi Shen		5. Date Nov 26, 2012	

1600 Riviera Avenue  
Suite 200  
P.O. Box 8025  
Walnut Creek, CA 94596-8025  
(925) 256-2700



November 26, 2012

49008400

**Submission of SS/CC Study**  
**NipsIt™ SUITE Cereals OF Seed Protectant**  
**EPA Reg. No. 59639-183**

Ms. Venus Eagle (PM 01, RD)  
Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Dear Mrs. Eagle:

Valent U.S.A. Corporation (Valent) is pleased to submit the storage stability and corrosion characteristics study per your request on 12-21-2011 to support the registration of NipsIt™ SUITE Cereals OF Seed Protectant, EPA Registration No. 59639-183.

Documents listed below are enclosed:

- EPA OPP Application form
- Data Transmittal Document which list the study being submitted.
- Study report of "Shelf-Life Storage Stability and Corrosion Characteristics of V-10304 0.37 FS"

If you have any questions, please contact me at (214)-784-5536 or via email:  
ssh@valent.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Sue-Chi Shen". The signature is fluid and cursive, with the first and last names being more prominent.

Sue-Chi Shen  
Project Manager  
Registration and Regulatory Affairs

## DATA TRANSMITTAL DOCUMENT

**ACTIVE INGREDIENT(S):** CLOTHIANIDIN, METCONAZOLE, METALAXYL

**PRODUCT(S):** NipsIt™ SUITE Cereals OF Seed Protectant

**EPA ID NUMBER:** 59639-183

**SUBMITTER:** Valent U.S.A  
1600 Riviera Ave  
Walnut Creek, CA 94596

**TRANSMITTAL DATE:** Nov 26, 2012

**REGULATORY ACTION SUPPORTED:** SUBMISSION OF STORAGE STABILITY AND CORROSION  
CHARACTERISTIC STUDY

VOLUME	GUIDELINE	STUDY	MRID
1		Title: CoverLetter_59639-183_120720 Author: Lab ID: Study Completion Date: Valent Accession No.:	
2	830.6317 830.6320	Title: Shelf-Life Storage Stability and Corrosion Characteristics of V-10304 0.37 FS Author: Nie C Lab ID: VP-37855 Study Completion Date: 2012-06-28 Valent Accession No.: 201200159	49008401



## INERT CLEARANCE STATUS FORM

Reviewer Name: Aswathy Balan			Request Date: 06/15/11
Tel: 703-347-8787	ISB	CUBE: S 4810	MAIL CODE:

### A. COMMENTS:

Ms. Sandra Rock in the inerts branch team accepted the ingredient RPD0048 Sunspense Red 48:2 under 40 CFR 180.920 for seed treatment uses and the registrant send a revised CSF with the ingredient Kathon CG/ICP preservative within the limits. Thus all the inerts are now approved for food use under 40 CFR 180.920, seed treatment use only.

### B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 897569	Date on CSF: 05/23/11	Food-Use Pesticide: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
EPA Reg. No/File Symbol: 59639-RIG	Formulation: Basic, Alt# 1, Alt# 2	
Product Name: NipsIt Suite Cereals of Seed Protectant		

### C. INGREDIENT INFORMATION:

Ingredient No.1	Tolerance Exemption(s) <sup>1</sup>					
	910	920	930	940	950	960
Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments: This ingredient is not approved for food use under 40CFR 180.920. This is approved for non-food use only.						

### Ingredient No. 2

Chem. Name:						
Trade Name:						
CAS Reg. No.:						
Comments:						

Reviewer Name: Aswathy Balan

Review Date: 06/15/11

<sup>1</sup>Language from the Code of Federal Regulations (40 CFR 180, subpart D):

40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.